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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|----------------------|---------------------|------------------|
| 10/586,688 | 11/06/2006 | Makoto Suematsu | K2100.0001 | 7334 |
| 32173 | 7590 | 06/01/2010 | | |
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| EXAMINER | | | | |
| NOBLE, MARCIA STEPHENS | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1632 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action
Before the Filing of an Appeal Brief

Application No.

10/586,688

Applicant(s)

SUEMATSU ET AL.

Examiner

MARCIA S. NOBLE

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 May 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because:
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-21.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632

Continuation of 3. NOTE: The proposed new claims, claims 28 and 29, comprise new limitations that have not been considered or search. Therefore, the proposed claims amendments are not being entered because they introduce new issues for search and consideration.

Continuation of 11. does NOT place the application in condition for allowance because:

112, 1st paragraph rejection

Claims 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A drug delivery method comprising administering the pharmaceutical composition of claim 12 to a damaged endothelial cell site of tissue comprising endothelial cells in a subject, and allowing said composition to accumulate on the damaged endothelial cell site, and;

A drug control method comprising administering the pharmaceutical composition of claim 12 to a damaged endothelial cell site if tissue comprising endothelial cells in a subject, allowing said composition to accumulate on the damaged endothelial cell site, and allowing the drug to act on the damaged site.

The specification does not reasonably provide enablement for a method that does not administer the carrier specifically to a site of endothelial cell tissue damage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant asserts that the proposed amendments to the claims overcome the rejection. Applicant's arguments are not found persuasive because the proposed amendment were not entered for reasons discussed above.

103a rejections

Claims 1-10 and 12-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Kazuo et al (JP 07-089874 (publication date: 4/04/1995; abstract is of record in the IDS, filed 7/20/2006; translation p. 1-23 provided by STIC translation), as evidenced by Dictionary.com (<http://dictionary.reference.com/browse/tinge>).

Applicant asserts that DPEA could not be recognized as a species of palmitic acid. Applicant asserts that while DPEA has a palmitic alcohol derived structures, it also has L-glutamate derived structures and succinate derived structures. Therefore, DPEA is not a species of palmitic acid. Applicant's argument is not found persuasive because palmitic acid structures are present in DPEA, thus making it a species of palmitic acid. Applicant further asserts that palmitic acid can not be used as a stabilizing agent by itself. This argument is not found persuasive because there is no requirement that palmitic acid function by itself or as a stabilizing agent. In fact it is working with other factors required by the claim, such as the cholesterol. Applicant asserts that the claims have been amended and overcome the rejection. Applicant's argument is not found persuasive because the proposed claims are not being entered as discussed above.

Claims 1-10 and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuchida (US 6,949,663 B2 date: 9/27/2005; effective filing date: 11/9/2001).

Applicant asserts that DPEA could not be recognized as a species of palmitic acid. Applicant asserts that while DPEA has a palmitic alcohol derived structures, it also has L-glutamate derived structures and succinate derived structures. Therefore, DPEA is not a species of palmitic acid. Applicant's argument is not found persuasive because palmitic acid structures are present in DPEA, thus making it a species of palmitic acid. Applicant further asserts that palmitic acid can not be used as a stabilizing agent by itself. This argument is not found persuasive because there is no requirement that palmitic acid function by itself or as a stabilizing agent. In fact it is working with other factors required by the claim, such as the cholesterol. Applicant asserts that the claims have been amended and overcome the rejection. Applicant's argument is not found persuasive because the proposed claims are not being entered as discussed above.